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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/381,484 | 02/28/2000 | DEBORAH A SCHADE | MJ-729 | 4022 |

7590 11/30/2004

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| EXAMINER | |
|---|---|
| WANG, SHENGJUN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/381,484 | SCHADE ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,14-17,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,14-17,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2004 has been entered.

### *Claim Rejections 35 U.S.C. § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 14-17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS) and Schweikhardt et al (IDS, 02/05/2004).

3. Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk, (which are about 26 mg/kcal of ARA and 8 mg/kcal of DHA, see applicants response of 11/17/03). The ratio of ARA:DHA is about 3:1 to 2:1. See the claims and the examples in columns 13-16. Kyle also teaches that the presence of ARA and DHA in infant food is critical for a healthy growth for infants. See, particularly, column 1, lines 29-53.

4. Kyle does do teach expressly the administration of the infant formula to preterm infants, or the particular ratio of ARA: DHA, and the particular amounts of ARA: DHA herein.

5. However, Crozier et al. teaches that the presence of ARA and DHA in food is particularly important for preterm infants to proper growth and development because they are unable to synthesize sufficient ARA and DHA. See, particularly, the summary. Schweikhardt et al. also teach to employ ARA and DHA enriched infant formula for feeding pretermed infant, wherein the ration of ARA and DHA is essentially the same as herein claimed. See, particularly, page 1, the third paragraph and the claims of the English translation. Schweikhardt et al. further teach an oil mixture for infant formula comprising 0.12 –1% of ARA and 0.05 –0.5% of DHA. These amount would translated to about 5-42 mg/kcal of ARA and 1.7 to 17 mg/kcal of DHA in a infant formula (based on 100 ml of infant formula contain 3.5 g of oil mixture and 120 ml of infant formula provide 100 kcal of energy (see table 1 at pages 5-6 of the translation).

6. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding pretermed infant.

7. A person of ordinary skill in the art would have been motivated to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding pretermed infant, because preterm infants are known to be in need of food with sufficient amount of ARA and DHA and the particular amounts of ARA and DHA herein are overlapped with the amounts range known in the art. The particular amount herein is considered obvious variation within the known range. Further, optimization of the amounts of ARA and DHA, or the formula as whole, particularly for preterm infants are considered within the skill of artisan since the criticality of

ARA and DHA for preterm infant growth is known in the art. Note the claimed ratio of ARA:DHA is within the broad range claimed by Kyle. See, particularly, claim 20 in Kyle. As to the limitation of "physical growth," note given the broadest interpretation, "physical growth" would read on the proper development of nerve tissue. "Physical" means "of or pertaining to the body, as distinguished from the mind or spirit; of or pertaining to matter things; " (The American Heritage Dictionary).

***Response to the Arguments***

Applicants' amendments and remarks submitted September 3, 2004 have been fully considered, but are not persuasive.

Regarding the limitation of "physical growth," note given the broadest interpretation, "physical growth" would read on the proper development of nerve tissue. "Physical" means "of or pertaining to the body, as distinguished from the mind or spirit; of or pertaining to matter things; " (The American Heritage Dictionary). Further, the examiner contends that the "proper growth and developments" as suggested by Crozier (see the abstract) would encompass the proper (full body) physical growth, as it should be understood in the art that proper nerve growth is essential to proper (full body) physical growth.

Applicants further argue that Crozier et al. actually teach away from the claimed invention since reference cited therein disclosed that feeding DHA to pretermed infant cause a decrease in growth. The arguments are not persuasive. Note the cited references as a whole suggest the administration of a combination of DHA and AA to provide benefit to pretermed infant, note DHA alone. Therefore, the fact that DHA alone may decrease the body growth, and the fact that both DHA and AA are essential for pretermed infant's proper growth would further

motivated one of ordinary skill in the art to used the infant formula enriched with both DHA and AA.

Applicants also assert that an unexpected result reside in the claimed invention, i.e., the "the catch up trend continued through 48 to 57 weeks which time the mean weight of group DA did not differ from group H which group C and D remained significantly lower." Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be ***unexpected and significant***. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, it must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e). In the instant case, there is no comparison data showing how and why the data in unexpected and significant. The cited references certainly suggest the benefit of the claimed method, even though the references do not expressly teach the degree of the benefit. Absent evidence to the contrary, the benefit presented herein would be considered within the expectation of the prior art suggestion, or just different from the prior art suggestion in degree, not in kind, which is not sufficient to establish a patentable distinctness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617